

Data Sharing Statement

Middleton PG, Mall MA, Dřevínek P, et al. Elexacaftor–Tezacaftor–Ivacaftor for Cystic Fibrosis with a Single Phe508del Allele. N Engl J Med. DOI: 10.1056/NEJMoa1908639.

Question	Authors' Response
Will the data collected for your study be made available to others?	Yes
Would you like to offer context for your decision?	Vertex is committed to advancing medical science and improving patient health through the responsible sharing of clinical trial data with qualified researchers. Proposals for the use of these data will be reviewed by a scientific board and approvals are at Vertex's discretion, and will be dependent on the nature of the request, the merit of the research proposed, and the intended use of the data.
Which data?	Only data elements needed to achieve the specific scientific aims of the proposal as outlined in the pre-specified analysis plan will be provided.
Additional information about data	Data will be anonymized in accordance with data privacy laws
How or where can the data be obtained?	After regulatory approval is achieved in all planned countries or regions, data can be obtained by submitting a complete research proposal and pre-specified analysis plan to CTDS@vrtx.com.
When will data availability begin?	If the proposal is approved, data will be made available once a Data Sharing Agreement is in place
When will data availability end?	Data availability will end as per the agreed terms of the Data Sharing Agreement
Will any supporting documents be available?	Yes
Which supporting documents?	Only documents that support the data requested in the approved proposal and pre-specified analysis plan will be provided.
Additional information about supporting documents	Documents will be anonymized in accordance with data privacy laws
How or where can supporting documents be obtained?	After regulatory approval is achieved in all planned countries or regions, supporting documents can be obtained by submitting a complete research

	proposal and pre-specified analysis plan to CTDS@vrtx.com.
When will supporting documents availability begin?	If the proposal is approved, supporting documents will be made available once a Data Sharing Agreement is in place.
When will supporting documents availability end?	Supporting document availability will end as per the agreed terms of the Data Sharing Agreement
To whom will data be available?	Data will be made available to qualified researchers.
For what type of analysis or purpose?	Data sharing is to enable post-hoc analyses in order to advance medical science.
By what mechanism?	Researchers are granted access to data and documents via a secure third-party website.
Any other restrictions?	—
Additional information	—

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